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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/357,423 07/20/99 BAER

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EXAMINER

CROSS, L

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

06/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

<b>Office Action Summary</b>	Application No. 09/357,423	Applicant(s) BAER, THOMAS M.	
	Examiner LaToya L. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 1999.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 5-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-4, drawn to a biological sample processing system, classified in class 436, subclass 174.
  - II. Claims 5-13, drawn to a fluidic circuit, classified in class 422, subclass 101.
  - III. Claims 14-15, drawn to a method of processing a sample, classified in class 436, subclass 174.
  - IV. Claims 16-20, drawn to a microdissected sample extraction device, classified in class 422, subclass 101.
  - V. Claims 21-22, drawn to an apparatus, classified in class 422, subclass 101.
  - VI. Claims 23-24, drawn to a method, classified in class 436, subclass 174.

The inventions are distinct, each from the other because of the following reasons:

The claims of groups I, II, IV and V are directed to four different devices/apparatuses which are unrelated as they each have different structures and/or components.

The claims of groups III and VI are directed to two different methods as the steps for carrying out each of the methods are different.

The groups of claims directed to devices/apparatuses are distinct from

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the groups of claims directed to the methods if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process can be carried out by a materially different apparatus such as a test strip.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Attorney Rimas Lukas on May 30, 2001 a provisional election was made with traverse to prosecute the invention of group I, claims 1-4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 recite the biological sample processing system comprises "a

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laminated film sample processing device including a reaction chamber mated with a biological sample carrier". In the manner in which the claims are written, it is unclear as to whether Applicant is claiming a three part system (comprising the laminated film sample processing device; reaction chamber; and sample carrier) or if Applicant is claiming that the reaction chamber and sample carrier are a part of the laminated film sample processing device.

Further, it is unclear what Applicant intends by "laminated film sample processing device".

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,940,250 to Plakas et al (hereinafter Plakas et al '250).

Claims 1-4 are directed to a biological sample processing system comprising a laminated film sample processing device including a reaction chamber mated with a biological sample carrier.

Plakas et al '250 teach a surface reaction system/instrument comprising a fluid supply unit, filtration unit, extraction unit, reagent dilution and supply unit, detection unit and recording unit which operate together to measure reactions of materials carried on

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a filter surface. Specifically, biological cells are detected as reactive materials in a test sample. According to Figure 1, filter film **(10)** is passed through the sample filtration unit where sample containing reactive materials is disposed on the filter film, resulting in a film carrying sample (sample carrier). The sample carrier is then advanced to extractors **(35, 36)** to permit extraction of the test sample which may contain a plurality of biological cells. The sample carrier film is then transported to light pipes **(12,13)** where luminescent reactions take place. See col. 2, lines 31-50 and col. 3, lines 23-50).

For reagent deposition, Plakas et al '250 teach a film **(11)** having reagents deposited thereon, from reagent feeders **(65, 66)**. Coupled to the reagent feeders is a metering pump and tube **(73)** for supplying dilution liquid. Dilution takes place in cylindrical cuvettes **(68)** or at the reagent feeder position. See col. 2, lines 51-68 and col. 4, lines 1-18.

Therefore, for the reasons set forth above, it is the position of the Examiner that the surface reaction system/instrument disclosed by Plakas et al '250 and comprising those components listed above, anticipates Applicant's claimed laminated film sample processing device including a reaction chamber and sample carrier.

#### ***Citation of Relevant Prior Art***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5,439,650 to Tsugita et al describes a reaction vessel comprising a

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reaction chamber (2) and a sample carrier (3) composed of magnetic material which is laminated with a film and disposed in the reaction chamber.

US Patent 6,084,237 to Troster et al describes an apparatus for analytical determination of trace compounds comprising a sample carrier whose surface is to be examined, a capillary, a light source, and an analysis apparatus.


US Patent 5,541,500 to Stapleton describes an apparatus for detection of genetic materials comprising a reaction chamber, samples immobilized on a thin, flat carrier, a reservoir for treatment liquids and a pump for moving the treatment liquids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC 810  
June 18, 2001

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700